

**Assessment of the USEPA Region 8  
Laboratory Certification Program for Drinking Water**

**Conducted by the**

**Office of Water  
Office of Ground Water and Drinking Water  
Standards and Risk Management Division  
Technical Support Center**

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## **Introduction**

The Office of Ground Water and Drinking Water (OGWDW) reviews the EPA regional drinking water certification programs annually including evaluation of the resources and personnel available to carry out the certification program. OGWDW's Technical Support Center (TSC) administers annual questionnaires and conducts triennial on-site regional laboratory certification program assessments (RLCPAs). The EPA Region 8 RLCPA was conducted June 6 - 8, 2016 at the EPA Region 8 laboratory in Golden, Colorado. The assessment team included Paul Grimmert and Michella Karapondo from TSC, with contract support from Laurie Potter and Laura Landes from The Cadmus Group. See Attachment A for a copy of the agenda and Attachment B for a list of attendees at the opening and/or exit meetings during the review.

The Manual for the Certification of Laboratories Analyzing Drinking Water<sup>1</sup> (the Certification Manual), Supplement 1<sup>2</sup> and Supplement 2<sup>3</sup> describe a process for the EPA regions to oversee the certification of the principal state laboratory (PSL), or a PSL network of laboratories, in states that hold primacy by assuring each state has the capability to analyze all regulated drinking water contaminants per federal regulations [40 CFR 142.10]. The PSL laboratories may be certified by the region, accredited through the National Environmental Laboratory Accreditation Program (NELAP), or recognized through a reciprocity agreement with another state laboratory certification program (SLCP). If the PSL does not perform analyses for all regulated drinking water contaminants for a state, the state is required to institute a laboratory certification program (LCP) to certify commercial and municipal laboratories that analyze drinking water compliance samples. The SLCP also may recognize a commercial or municipal laboratory that has been certified or accredited by another state through reciprocity. The EPA regions are responsible for assessing the adequacy of the SLCP. Each region holds primacy for all non-primacy states, including tribal governments that oversee public water systems [40 CFR 141.2] and certifies, or recognizes through reciprocity, those laboratories analyzing such compliance samples.

In this report, TSC describes their assessment of the EPA Region 8 LCP, which assesses SLCPs and certifies PSLs in five primacy states and the EPA Region 8 Wyoming Direct Implementation (DI) program. Commendations, findings, and recommendations are summarized below.

## **1. Assessment Summary**

### **a. Commendations:**

1. The EPA Region 8 LCP is highly effective at maximizing resources and defining vulnerabilities. For example, the RLCPM (Marcie Tidd) has prepared white papers and memos for the Laboratory Director and the Program Office on the vulnerabilities to keep everyone apprised about progress to address problems detected in previous assessments. She is proactive in organizing staff for audits and creatively sought assistance for the program. For example, she recruited help from certification officers (COs) in other regions to perform

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<sup>1</sup> Manual for the Certification of Laboratories Analyzing Drinking Water, Fifth Edition, 2005, EPA 815-R-05-004.

<sup>2</sup> Supplement 1 to the Fifth Edition of the Manual for the Certification of Laboratories Analyzing Drinking Water, Supplement 1 to EPA 815-R-05-004, June 2008, EPA 815-F-08-006.

laboratory audits and coordinated smoothly with multiple parties to ensure audit findings and observations were tracked through closure and certification letters.

2. EPA Region 8 COs are experienced, technically proficient staff who perform thorough work, based on interviews of the chemistry COs and careful review of microbiology reports and checklists.
3. The region's tracking system for its schedule to conduct SLCPAs and PSL Audits is clear and well-maintained. Resource planning is coordinated between the EPA Region 8 drinking water program office in Denver, Colorado and the laboratory director and RLCPM in Golden, Colorado.
4. The region thoroughly documents review of PT sample results, including results for laboratories seeking reciprocity.
5. SCLPA and PSL audit files contain exemplary documentation and reflect a conscientious effort to include detailed observations about findings and corrective actions required, using a standardized report format described in a separate SOP. Corrective action reports were good and traceable with documented communication between the region and the state.
6. The RLCPM's observation and participation in the NELAP-AB accreditation of the Utah program provide strong oversight of that lab accreditation program, plus the region conducts its own assessment of the state's LCP.
7. To improve the quality of water samples submitted to laboratories, and minimize questions to the region's laboratory, the EPA Region 8 LCP created an outreach piece on sample collection procedures which has been used nationally.
8. Most recommendations and findings from previous RLCPA were addressed (except specified findings below).

#### **b. Findings**

1. More FTE and travel resources are needed to meet the program requirements. This is a repeat finding from the previous two RLCPAs. Without additional resources, the RLCP cannot complete all required triennial SLCPAs, PSL audits, and Wyoming and tribal laboratory audits. The regional laboratory has committed to perform the five SLCPAs and PSL audits over the triennial cycle. In the year when the region performs one PSL audit, the COs will audit one of the laboratories in Wyoming, if it is within driving distance, e.g., Cheyenne or Laramie. However, the remaining Wyoming and tribal laboratories are not included on the audit schedule.

**Region 8 Response to Finding 1:** The R8 laboratory agrees with this finding. This a repeat finding, with the LCP losing three COs since the 2013 audit. Another CO is retiring in 2017, leaving the laboratory down four COs. This is an issue which has been repeatedly brought to management in the form of briefings and vulnerability / options documents. A "Resource Options and

Vulnerabilities” document has been prepared to brief upper management, and the R8 LCP has been listed on the Region’s FMFIA vulnerabilities list. Additionally, this Assessment Report will be shared with Regional management.

Offers have been made to onboard two COs for the laboratory (a chemist and a microbiologist), however it is unknown how the current hiring freeze will affect this. An additional two COs (beyond the current offers) would still be needed to bring the program to a minimal capacity.

2. EPA Region 8 should document how the region will complete the laboratory audits required for the Wyoming DI program. Without additional resources, the region’s COs will only be able to audit 1 or 2 of the 14 in-state laboratories and 40 laboratories certified through reciprocity over the next 3-year audit cycle. It also is uncertain whether EPA Region 8 can continue to rely on other EPA regions to help with the audit workload. Absence of this plan represents a serious vulnerability, as these laboratories are analyzing compliance samples.

**Region 8 Response to Finding 2:** This is a shared concern. The R8 Lab Manager and RLCPM have prepared resource options and vulnerabilities documents to address the immediate needs for 2017 laboratory audits as well as long term needs, and this Assessment Report was shared with Regional management. As is the case for Finding #1, this is an issue that will need to be addressed at the Office or Regional level.

3. EPA Region 8 should ensure all SLCPAs are completed on the triennial cycle. There were no records on-site of a SLCPA being conducted for Montana, however TSC had records of the last SLCPA for Montana occurring in 2012. The SLCPA for South Dakota is overdue, with the last SLPCA taking place in 2012. The SLCPA for Montana and South Dakota should be completed as soon as possible as it represents a serious vulnerability.

**Region 8 Response to Finding 3:** R8 agrees that SCLPAs are an important component of the LCP. Ultimately the ability to conduct all SCLPAs on a triennial cycle is resource-dependent. Note Section 2 of this report, which states the R8 should have at least one FTE dedicated to the regional LCP and one (if not two) additional FTE for Wyoming direct implementation. Currently the RLCPM fulfills both of these roles, in addition to functioning as a CO and laboratory analyst. When the RLCPM attends an audit of a State PSL, she also conducts the on-site SCLPA. If a microbiology CO other than the RLCPM performs a PSL audit, the SCLPA may not be conducted for that cycle. Annual surveys are submitted to each of the R8 States, which serve as an annual SCLPA. Every attempt will be made for the RLCPM to rotate states

within the triennial cycle, so that an on-site SCLPA can be conducted at each at least every 6 years.

With regard to the SCLPA for Montana, the referenced 2012 records are on-site and among those provided to auditors during their visit. The report was not sent with pre-audit documentation, as the 2013 auditors commented that the Montana SCLPA was not a formal evaluation report, and more of an internal document. R8 acknowledges that Montana and South Dakota are in the most immediate need of a SCLPA and will direct resources to this when available.

**c. Recommendations**

1. EPA Region 8 should develop a Memorandum of Agreement (MOA) between the EPA Region 8 drinking water program office and the EPA Region 8 LCP. The document should indicate the FTEs needed to maintain the current LCP, as well as any additional FTEs necessary for reviewing and tracking reciprocal certifications of laboratories in WY, and for auditing laboratories for the Wyoming DI program and the RLCP.

**Region 8 Response to Recommendation 1:** An MOA had previously been drafted between the Office of Technical and Management Services and the former Office of Partnerships and Regulatory Assistance (the new Office of Water Protection now houses the R8 Drinking Water Program (DWP)). The document will be revisited with new program management.

2. EPA Region 8 should replace any vacancies that occur in the program with COs with similar skill sets to ensure there is no loss of capability.

**Region 8 Response to Recommendation 2:** The R8 Laboratory agrees with this recommendation. The offers made for new hires are for a qualified microbiologist and chemist. Any additional FTE advertisements would be for the same disciplines.

3. Both EPA Region 8 and the assessment team have previously identified the vulnerability of having only one CO in the Colorado LCP. The region should continue monitoring whether the state has adequate staffing to meet the LCP requirements.

**Region 8 Response to Recommendation 3:** The R8 Laboratory agrees that this is a vulnerability, and has communicated this to the State through SCLPAs and verbal communication. Annual questionnaires are sent to the Colorado LCP, and the next on-site SCLPA will coincide with the chemistry and microbiology evaluations in early 2018.

4. The Sitting Bull laboratory should be formally notified that it has been decertified, and an agreement should be reached between the EPA Region 8

drinking water program office and the regional laboratory that the laboratory will not be recertified until/unless it provides key materials before the audit, such as valid SOPs, Initial Demonstration of Capability (IDC) documents for current analysts, and successful PT samples. If the laboratory wishes to analyze compliance samples, this decision may need to be revisited.

**Region 8 Response to Recommendation 4:** In previous discussions with the R8 DWP, resources were not allotted to audit the Sitting Bull laboratory, as they've never submitted a compliance sample. The laboratory is still interested in certification. R8 LCP personnel will enter into discussions with the R8 DWP to make a final decision on this laboratory. The decision to issue a formal decertification will need to come from both programs.

5. All Wyoming laboratories and their audit status by discipline (e.g., microbiology, chemistry, and radiochemistry) should be included on TSC's Annual Questionnaire.

**Region 8 Response to Recommendation 5:** All laboratories in Wyoming have been included in TSC's annual questionnaire since at least 2011 (when the current LCPM started). We can also send a copy of our certified laboratory list for Wyoming and R8 Indian Country, which includes all reciprocal certifications and their disciplines (roughly 40).

6. The SOPs for SLCPAs and PSL audits should be reviewed and updated, as they were last reviewed in 2012. EPA Region 8 should consult their QA document to confirm its requirement for review of SOPs and review the SOP on that schedule. Note that the PSL Audit SOP states it shall be reviewed at least every two years. If no schedule is indicated for the SLCPA SOP, EPA-QA/G-6 says review of SOPs should be done periodically, for example, every 1 or 2 years.

**Region 8 Response to Recommendation 6:** The R8 LCP is in agreement that the programmatic SOPs are due for an update. It is our intent to update these in calendar year 2017. The R8 Laboratory has intermittent QA days scheduled solely for the update of SOP documents.

7. The following detail should be added to the SLCPA and PSL audit SOPs:
  - Table of Contents to SLCPA SOP.
  - Definitions. Add definitions for ratings used, including "effective," "minimally effective," and "not effective."
  - Process to conduct the SLCPA. How the region will make its assessment should be explained in more detail, as it is in the SOP for a PSL audit.
  - Description of procedures or role of region in oversight of SLCPAs and laboratories accredited by a NELAP-AB.

- New records schedule, if a new schedule is finalized. EPA HQ-OW and the regions are moving to the new schedule (1016 (c)) which requires the program to keep files for 10 years.
- Edit to title of the PSL audit SOP. Consider deleting “PSL” from title of the SLCPA SOP named “R8LAP-003v1\_PSLProgramRvw” to avoid possible confusion that this SOP describes the PSL audit.
- Copy of pre-audit questionnaire for PSL audits.
- Use of checklist during audits. Discuss process to complete checklists and address how checklists will be saved in the Data and Records Management section.
- Copies or reference link to SOPs or other tools used during assessments should be filed with completed reports in regional files.

**Region 8 Response to Recommendation 7:** The R8 LCPM will consider incorporation of these elements when revising the SOPs mentioned.

8. The reciprocity SOP should include a plan to address gaps in laboratory capacity or capability revealed through PT results review when no laboratory has applied for certification for a primary contaminant(s).

**Region 8 Response to Recommendation 8:** The reciprocity SOP describes the process for reviewing documentation from laboratories outside of Wyoming, and the issuance of certification letters for Wyoming and IC public water system samples. This may not be the best venue for primacy discussions. Ultimately the published list of certified laboratories serves as Wyoming and R8 IC’s capacity network. Additionally, the R8 DWP has indicated that they will accept data from any laboratory certified by a R8 State.

9. During SLCPAs, the region should ensure that states have a plan in place to address gaps or missing contaminants. This step is particularly for the Wyoming DI program to ensure that Wyoming public water systems have adequate laboratory capability and capacity to have all compliance samples analyzed.

**Region 8 Response to Recommendation 9:** For Wyoming and R8 IC systems, the published list of certified laboratories serves as Wyoming and R8 IC’s capacity network. Additionally, the R8 DWP has indicated that they will accept data from any laboratory certified by a R8 State.

For R8 primacy states, we’ve asked on their annual survey which required contaminants they do not hold certification for. Additionally, when a State PSL loses capacity, they are asked to identify alternate laboratories. In a recent monthly teleconference between OGWDW/TSC and the Regions (March 7, 2017), it was unclear whether states needed to hold MOUs,

contracts, verbal agreements, or whether certification of laboratories would be sufficient to address gaps in missing contaminants. The R8 LCPM will be happy to address this issue in future SCLPAs, in whatever format is decided upon by TSC.

10. The region should ensure a date appears on both electronic files and hard copies.

**Region 8 Response to Recommendation 10:** It is general practice to date all files related to the LCP. We will make every effort to continue to do so moving forward.

11. Tracking corrective actions and other follow-up from SLCPAs and laboratory audits is time-consuming as the tracking is done manually. The region would benefit from an electronic tracking system.

**Region 8 Response to Recommendation 11:** The R8 LCP is in agreement with this recommendation. We welcome any suggestions on electronic tracking systems. This is something that is dependent upon available resources, but we will discuss the issue with our information technology specialist once he returns to the laboratory this spring. If OGWDW/TSC had available resources to look into this, such a system may be something all EPA Regions could benefit from.

12. The regional and state staff should attend CO refresher training if it has been more than five years since their last training. This is a repeat recommendation.

**Region 8 Response to Recommendation 12:** The R8 LCP recognizes that this is an important recommendation from the Certification Manual, and most of its COs are due for a refresher training. The R8 Laboratory funding for travel is relatively low, and has been reserved for conducting audits and field sampling events. Requests to attend refresher training are made in most years, though funding is not available. In 2017, the LCP has submitted a request to send one existing laboratory chemist, and plans on making an additional one to two requests for any possible microbiology or chemistry new hires. The attendees will be expected to present updates and highlights from the training to existing COs.

13. The region would benefit from a more advanced electronic method for PT tracking. Optimally, the region would like access to an automatic database which will track PTs on its own using CSV or other data files directly from the providers and provide a report to the region. If this is not feasible, the region's Excel spreadsheet could be updated as results are received, or as close to real time as possible.

**Region 8 Response to Recommendation 13:** The R8 LCP is in agreement with the recommendation that a PT tracking system would be beneficial. If



resources were available, this would be a tremendous time-saver. The LCPM has requested such a system in the past and will continue to do so. It would also be ideal to update Excel spreadsheets when results are received; however, with the number of labs the LCP is responsible for, we just don't have the resources at present to do so. This is another instance of something all EPA Regions may be able to benefit from if OGWDW/TSC had resources available to develop a database system.

14. A consistent policy for certification is needed if a laboratory fails a PT in the previous year and no new PT sample has been provided by the time the region makes its annual certification decision. The assessment team recommends that the region should issue Provisional Certification with a shortened expiration date that allows time for the laboratory to submit PTs.

**Region 8 Response to Recommendation 14:** The Certification Manual states that “At least annually drinking water laboratories certified for chemical contaminants **must** satisfactorily analyze a PT sample to maintain certification (40CFR 141.23(k)(3)(i), 141.24(h)(17)(i)(A) and 141.89(a)(i)(1)(i)).” If a laboratory has only failed PT tests in the previous year, R8 COs have no confidence that the laboratory can accurately analyze drinking water compliance samples for the affected method and analyte. Provisional Certification still allows the laboratory to analyze compliance samples; which could be a public health risk. There are instances when provisional certification is issued, when the CO has confidence that the laboratory is producing acceptable data; but R8 maintains that this should be a matter left to the professional judgement of the CO and LCPM.

15. The region should comply with its SOP and the requirements of the Certification Manual and hold an annual update with the states. The region could encourage its primacy states to take advantage of the annual webinar on regulatory update under development by TSC to satisfy this requirement.

**Region 8 Response to Recommendation 15:** This is another topic related to lack of resources. If the R8 LCP were staffed to full capacity, the LCPM could divert time to the annual update. Currently the LCPM holds calls and webinars when there [are] pertinent regulatory updates, and also engages in frequent email communications with the states. The last webinar was held in 2016. R8 does fully plan to encourage states to take advantage of TSC's regulatory update webinar when it's developed.

16. Notes and checklists from SLCPAs and audits should be scanned and kept in a central location. (Regions 9 and 7 type checklists and attach them to the reports.) A fillable PDF would be helpful and more efficient, but requires resources to develop.

**Region 8 Response to Recommendation 16:** At present each CO maintains their own records, so that they can refer back to them when laboratories contact them regarding corrective actions or technical assistance. Moving forward, we will make every effort to scan or copy those checklists and keep them with the central file.

## **2. EPA Region 8 Laboratory Certification Program Overview**

The Region 8 drinking water program is located in the EPA Region 8 offices in Denver, Colorado, while the Region 8 drinking water LCP is located at the regional laboratory in Golden, Colorado. The Region 8 Certification Authority (CA) has been delegated to Richard Buhl, the assistant regional administrator in Technical Management Services (TMS). Marcie Tidd is the RLCP manager (RLCPM). The seven regional certification officers (COs) are Michael Bade (Inorganic Chemistry), Jesse Kiernan (Organic Chemistry), Jeff McPherson (Microbiology), Mark Murphy (Organic Chemistry), David Nguyen (Organic Chemistry), Tom Slabe (Organic Chemistry), and Kenneth Dahlin (Organic Chemistry). Melissa Beedle was slated to take the Chemistry CO course in July 2016, but funding was cut (she is expected to attend the June, 2017 course). Their certification responsibility and EPA training status are included in Attachment C. These DW Laboratory Certification Program staff are located at the regional laboratory in Golden, Colorado.

The EPA Region 8 LCP oversees LCPs and PSLs/PSL networks in five primacy agencies, including Colorado, Montana, North Dakota, South Dakota, and Utah. The region also serves as the LCP for the Wyoming DI program, which certifies 14 in-state laboratories and approximately 40 laboratories through reciprocity. Attachment D includes a table showing the number of certified laboratories in each state. EPA Region 8 does not audit the laboratories for any tribes.

The RLCPM, the regional laboratory director, and the CA are in regular contact with EPA Region 8 drinking water program staff regarding laboratory certification issues, as well as those relating to data reporting and test methodology. The RLCPM co-leads webinars with drinking water program staff, plans annual audits with them, and fields inquiries from the drinking water personnel on a roughly weekly basis. Communications are usually documented in emails.

EPA Region 8 LCP has the most certification workload of all regions with the combined responsibilities for the RLCP and the LCP for Wyoming DI, and has well-qualified staff, but the program faces serious resource shortages. Since 2011, the regional laboratory has lost four scientists and most were also COs. The staffing shortage affects workload to perform SLCPAs and audit PSLs, and very limited capacity for regional COs to audit the laboratories certified by the Wyoming LCP in the upcoming triennial cycle. The region has not performed an on-site SLCPA in Montana since 2006, and the South Dakota SLCPA is overdue. Other regions have assisted the region by conducting audits, but the RLCPM doubts that enough support can be provided by other regions to meet the schedule. The 2013 RLCPA stated “With the scope and size of the EPA Region 8 LCP, it seems reasonable that EPA Region 8 would have at least one FTE dedicated to the EPA Region 8 LCP, and at least 1 (if not 2) additional FTE exclusively dedicated to the implementation of the laboratory certification program for Wyoming (as is typical for any primacy state).” A March 2016 white paper prepared by the RLCPM titled “2016 Vulnerabilities and Options for the EPA Region 8 Drinking Water Laboratory Certification Program” documents options for meeting the workload, explains the need for additional resources, and reaffirms that 2 FTEs over 2013 staffing levels are needed in addition to the RLCPM to meet the LCP requirements.

Attachment E lists the state COs for each EPA Region 8 state, their areas of responsibility, and their EPA training status. Most of the state COs in Region 8 have attend the CO training in the past five years, as recommended in the Certification Manual. One CO in both Colorado and Montana is overdue to complete a refresher course, and both COs for South Dakota have very outdated training or there are no records of attendance.

### **3. EPA Region 8 State Laboratory Certification Program Assessments**

To meet the Certification Manual's recommendation for yearly review of the SLCP, EPA Region 8 asks the states to complete the TSC Annual Questionnaire, then collates responses for TSC and adds notes of any interactions with SLCPs during the year. All states in the region responded fully to the 2015 Annual Questionnaire.

The EPA Region 8 SOP is a controlled quality document, and contains signature approval indicating that it has been both reviewed and approved by management. It is based on the approach outlined in the EPA Certification Manual. The SOP contains most administrative/programmatic elements listed in EPA-QA/G-6 (title page, procedures, quality control and quality assurance, and references). The SOP is missing a Table of Contents and more detail on procedures. Specifically, expansion is needed on topics 5.1.1.1. through 5.1.1.8. and 5.2.3.1 through 5.2.3.4. The management of assessment checklists, referenced in the discipline sections above (chemistry, microbiology, and radiochemistry), should be included in section 6.1. Section 6.1.4 should state that findings require corrective action plans, and plans should be deemed "acceptable" by the region. Sections 6.2 through 6.4 require more specifics, e.g. filenames, directory locations, and a basic format for organization for records. The region has developed detailed checklists to use during assessments.

At least triennially, the region performs onsite assessments of the SCLPs, and the region is current on assessments for all state LCPs audited and certified by EPA Region 8 except Montana and South Dakota. Montana's program has not been formally assessed on-site since the current RLCPM joined the program in 2011. The South Dakota SLCPA was partially completed by the RLCPM and the checklist given to a CO, but the assessment was never completed. (The RLCPM plans to complete the review in 2016 using a telephone interview.) The review by the TNI NELAP-AB and EPA of the dual program in Utah is also current. Dates of the most recent SLCPAs for each state are reported in the table in Attachment D.

The RLCPM and R8 COs frequently offer technical assistance to the primacy states. Regional files contain documentation about the topics discussed and copies of emails. Although the region has not been hosting annual meetings, there is routine communication with states via email and phone about relevant issues. These communications also are documented in the files.

During the SLCPAs, the region and NELAP-ABs review reports, PT results, SOPs, a list of which assessors are qualified for what parameters to confirm that COs meet qualifications, training records, management reviews, and the annual Quality Assurance report. The region conducts interviews of staff, reviews laboratory files, and examines the state's corrective action database.

The RLCPM has been actively participating in the TNI review of the Utah TNI-based laboratory accreditation programs. The assessment team noted that Ms. Tidd fully participated in the evaluation panels, and the evaluations were complete, with all drinking water concerns addressed. Utah is a dual program and the RLCPM participates in both the TNI NELAP-AB evaluations as a

team member and conducts separate reviews of the program. No EPA Region 8 state uses third party assessors.

The region does not have a formal fraud reporting and ethics program for drinking water and fraud is not addressed in the region's SOP. EPA Region 8 auditors are all analysts in the fields they audit and are aware of opportunities to commit fraud and sensitive to suspicious data.

#### **4. EPA Region 8 Principal State Laboratory Audits**

The EPA Region 8 SOP to conduct audits of the PSLs is a controlled quality document. The SOP is detailed and covers most elements for an audit described in the Certification Manual. The following items were missing: Table of Contents; copies of pre-audit questionnaires, checklists, interview script, and other tools used during an audit to support the report; definitions for ratings used, including "effective," "minimally effective," and "not effective"; description of procedures or role of region in oversight of SLCPAs and laboratories accredited by a NELAP-AB.

All PSL audits in the last triennial cycle were completed on schedule. Three Wyoming laboratories were not audited on a three-year frequency in the last audit cycle. The dates of the most recent audits for all Wyoming laboratories and the one tribal laboratory are 2013 or later, but the resource shortfall for the EPA Region 8 LCP shall profoundly affect audits of Wyoming laboratories in the next audit cycle. As of 2016, the Region 8 COs will only be able to audit 1 or 2 Wyoming labs that are within driving distance, such as Cheyenne and Laramie, over the 3-year audit cycle. This will not meet the triennial schedule for audits to certify the 14 in-state laboratories and 40 laboratories certified through reciprocity.

The region's audits of PSLs for chemistry, microbiology, and radiochemistry are current for all PSLs audited by the region. TNI audits are also current. However, the current profile does not accurately forecast the strength of the RLCP. In the past, the EPA Region 8 LCP received funding from OPRA (the office containing the R8 drinking water program) to perform some audits for the Wyoming DI program and also funding to hire chemistry and microbiology third party auditors, using the OGWDW Water Security Division mission contract. The laboratory has not received contract funding since 2012, though travel funds have since been provided. The RLCPM asked for help from other regions, and EPA Regions 6, 7 and 9 helped with EPA Region 8's audits. In 2016, the EPA Region 8 Laboratory Director committed to perform all state PSL audits on a three-year schedule. In the year when EPA Region 8 only must perform one PSL audit, the COs will audit one of the laboratories in Wyoming. The laboratory must be within driving distance, e.g., Cheyenne or Laramie. Other audits of Wyoming laboratories cannot be performed because the RLCPM cannot manage the logistics for the audits, perform her RLCPM and CO roles, and complete her laboratory work. It is uncertain whether OPRA will arrange and oversee audits for the remaining Wyoming laboratories.

Region 8 is responsible for ensuring that all laboratories analyzing drinking water compliance samples for Wyoming water systems are certified. Region 8 either certifies Wyoming laboratories directly or issues reciprocal certification allowing analysis of Wyoming drinking water samples to laboratories that have been certified through other State drinking water LCPs. The Region 8 SOP for reciprocal certifications details a review of the state certificate, PTs, last audit report, and QA manual. While this practice is ideal for issuing reciprocal certification to reduce vulnerabilities to the region, it is resource intensive.

As recommended in the 2013 RLCPA, EPA Region 8 also does not plan to audit the Sitting Bull laboratory. In the past, the regional COs have audited the laboratory and spent one to two weeks providing technical assistance to help the laboratory pass certification, as well as significant time tracking corrective actions and troubleshooting operations. However, the laboratory is staffed by students and when the trained students graduate, new students replace them and must be retrained. This loss of capability has prevented the laboratory from achieving a sustainable program and the laboratory has not been able to pass PTs consistently.

Due to limited resources, the region does not observe the state COs during an audit. However, the region did work closely with the Colorado CO during an audit as part of an investigation into a complaint, and was impressed with his knowledge and expertise. The RLCPM also noted his reports do not reflect the detail of his audits, potentially because he has such a heavy audit schedule that there is inadequate time to write lengthier reports.

The RLCPM accompanies TNI during the SLCPA and PSL audit for Utah, and reviews the report and PTs for the state as part of its decision to award certification. The state conducts a separate audit as well.

The EPA Region 8 audit reports are thorough and timely. Microbiology audit checklists are in the shared files, and chemistry audit checklists are stored in individual CO's files. The assessment team found corrective action plans (CAPs) and correspondence between the region and laboratory directors regarding most reports. The RLCPM ensures the states prepare a CAP, and obtains updates on CAs. There is no electronic tracking system used in the region to track implementation of corrective actions or close-out of the audits, however this information is tracked on a whiteboard in the RLCPM's office.

Certificates list the method and analyte, as well as the expiration date. The certificates note that they are valid as long as the laboratory follows the methods and provides successful PTs. The tracking spreadsheet which schedules and tracks completion of SLCPAs and laboratory audits also includes the certification status of each laboratory by method and analyte. The spreadsheet is on a shared drive.

The region reviews and organizes PSL PT samples in binders organized by state, and are filed electronically as well. PTs are tracked manually in a spreadsheet, but no electronic tracking system is in place to determine if PTs are missing.

In the 2016 North Dakota chemistry audit, the assessment team found PT failures were treated inconsistently. PT failures had occurred for three contaminants in 2015 and the laboratory had not yet provided successful PTs in 2016. The responses were different: hexachlorobenzene (Method 508) was listed as Provisional Certification and Endrin and hexachlorocyclopentadiene (Method 525.2) were Not Certified. For PSLs that failed PTs during microbiology audits, the region also gave Provisional Certification with a shortened expiration date.

Some states did not offer analysis for all primary drinking water contaminants. For example, the regional laboratory (which serves as the Wyoming PSL) is not *accredited* for semi-volatiles using Method 524.3 because the Texas Commission on Environmental Quality (the NELAP accreditation body that audited the laboratory) only offers accreditation for 524.2. Utah does not have certification for asbestos. Montana is not certified for dioxin. The region's report should include the plan to address these shortcomings, should there be a need for analysis of compliance samples for these contaminants or methods.

Findings in some audits referenced requirements in wastewater methods, and were too stringent to apply to a drinking water audit. For instance, the Colorado 2015 audit report included a finding that “observed that Picloram coefficient of determination (R<sup>2</sup>) was < 0.99. R<sup>2</sup> should be > 0.99.” This technically is not a finding, as there are no R-squared linearity criteria for this method. The method requires an average response factor calculation, or equivalent. Section 10.2.2 states: “starting with the standard of the lowest concentration, process each calibration standard according to Section 11.1 and tabulate response (peak area) versus injected quantity in the standard. The results can be used to prepare a calibration curve for each compound. Alternatively, if the ratio of response to concentration (response factor) is a constant over the working range (20% RSD or less), linearity through the origin can be assumed and the average ratio or response factor can be used in place of a calibration curve.”

## **5. Records Management**

The SOPs for the SLCPAs and PSL laboratory audits thoroughly describe the process to manage PT results, and information collected or reported during the assessments and audits.

Currently, the Certification Manual requires that records be kept for 6 years, but the EPA’s Office of Information has been contacted to inquire whether Schedule 1016 (c) for a 10-year retention policy may be more appropriate. The region’s SOPs conform to the current six-year requirement.

Files contain copies of recent reports, correspondence, checklists, corrective action reports, and certification letters for PSLs. Records were available for at least two triennial cycles. PSL audits are further subdivided with PTs, reports, correspondence, certificates, and corrective action reports. A list of file notes is kept on the inside cover of each folder which tracks the status of audits, certifications, and corrective action reports, from initial correspondence through issuance of the certification letter. Completed checklists from microbiology audits used during on-site visits are in the files, but the checklists for chemistry are stored in the CO’s personal records. Emails are printed periodically and stored in the state files.

All files are shared on an electronic drive available to all staff, except working notes and checklists used by certification officers (COs) during audits which are retained in the CO’s personal files. The files show an improvement since the last RLCPA.

## **6. Communication and Technical Assistance**

The region provides regular technical assistance to state PSLs and the Wyoming and tribal laboratories upon request. Most requests for assistance are about interpretation of method requirements. Email or other correspondence is maintained to document the technical assistance provided.

The RLCPM also routinely discusses program issues with the EPA Region 8 drinking water program staff and management as issues arise. Communications are usually documented in emails.

However, the region does not hold annual updates with the state as required by its SOP and the Certification Manual. The RLCPM indicated that the primacy states are not interested in this update, so she has faced opposition to proposed calls or meetings.

## Attachment A

### Agenda: EPA Region 8 Laboratory Certification Program Assessment

<b>Regional Review – Region 8 Laboratory Certification Program</b>			
<b>Tentative Agenda</b>			
<b>Monday, June 6</b>		<b>Location</b>	<b>Invitees</b>
2:30 PM – 3:30 PM	Opening conference		TSC, Cadmus, Marcie Tidd, other staff/management from regional laboratory or program office
3:30 PM – 5:00 PM	Begin regional file review		TSC & Cadmus
<b>Tuesday, June 7</b>			
9:00 AM – 12:00 PM	Continue regional file review		TSC & Cadmus
12:00 PM – 1:00 PM	Lunch		
1:00 PM – 5:00 PM	Continue regional file review		TSC & Cadmus
<b>Wednesday, June 8</b>			
9:00 AM – 12:00 PM	Continue regional file review		TSC & Cadmus
12:00 PM – 1:00 PM	Lunch		
1:00 PM – 2:30 PM	Continue regional file review		TSC & Cadmus
2:30 PM – 3:00 PM	Summarize assessment findings		TSC & Cadmus
3:00 PM – 4:00 PM	Exit meeting/review of findings		TSC, Cadmus, Marcie Tidd, other staff or management from regional laboratory or program office

## Attachment B

### Attendees at Meetings for the June 2016 EPA Region 8 RLCPA

	Participant	Program	Role	Meeting
1.	Mark Burkhardt	EPA Region 8	Regional Laboratory Director	Opening and exit meetings
2.	Marcie Tidd	EPA Region 8	RLCPM	Opening and exit meetings
3.	Jesse Kiernan	EPA Region 8	Regional CO	Opening and exit meetings
4.	Melissa Beedle	EPA Region 8	Regional CO	Opening and exit meetings
5.	Thomas J. Slabe	EPA Region 8	Regional CO	Opening and exit meetings
6.	Kenneth Dahlin	EPA Region 8	Regional CO	Opening and exit meetings
7.	Mark A. Murphy	EPA Region 8	Regional CO	Opening and exit meetings
8.	Patrice Kortuem	EPA Region 8	TMS DARA	Opening and exit meetings (by phone)
9.	Michael Bade	EPA Region 8	Regional CO	Exit meeting
10.	William Batschelet	EPA Region 8	Regional CO	Exit meeting
11.	Paul Grimmatt	EPA OGWDW/TSC	TSC Lead Assessor Assessment Team	Opening and exit meetings
12.	Michella Karapondo	EPA OGWDW/TSC	TSC Assessment Team	Opening and exit meetings
13.	Laurie Potter	The Cadmus Group	Contractor Assessment Team member	Opening and exit meetings
14.	Laura Landes	The Cadmus Group	Contractor Assessment Team member	Opening and exit meetings



## Attachment C

### Area of Responsibility and Training Status of Regional Laboratory Certification Program Personnel

<b>Title</b>	<b>Name Office/Branch</b>	<b>Area(s) of Responsibility</b> (Specify Chemistry, Microbiology, Radiochemistry, <i>Cryptosporidium</i> , etc.)	<b>Year Passed EPA CO Training</b>	<b>Year Last Audited EPA CO Training</b>	<b>Year of most recent audit by CO</b>
<b>Regional Administrator</b>	Shaun McGrath 1595 Wynkoop, Denver CO Mcgrath.shaun@epa.gov 303-312-6308	-----	n/a	n/a	n/a
<b>Regional Certification Authority (CA)</b>	Richard D. Buhl Assistant Regional Administrator Technical & Management Services 1595 Wynkoop, Denver CO Buhl.richard@epa.gov 303-312-6920	-----	n/a	n/a	n/a
<b>Regional Laboratory Director</b>	Mark Burkhardt 16194 W. 45th Drive, Golden CO Burkhardt.mark@epa.gov 303-312-7799	n/a	n/a	n/a	n/a
<b>Regional Laboratory Certification Program Manager (RLCPM)</b>	Marcie Tidd Microbiologist, R8 Laboratory 16194 W. 45th Drive, Golden CO Tidd.marcie@epa.gov 303-312-7764	Microbiology	2011	n/a	2016
<b>Regional Certification Officer (Regional CO)</b>	Michael Bade Inorganic Chemist, R8 Laboratory 16194 W. 45th Drive, Golden CO bade.michael@epa.gov 303-312-7765	Inorganic Chemistry	1996	2007	2016

<b>Title</b>	<b>Name Office/Branch</b>	<b>Area(s) of Responsibility</b> (Specify Chemistry, Microbiology, Radiochemistry, <i>Cryptosporidium</i> , etc.)	<b>Year Passed EPA CO Training</b>	<b>Year Last Audited EPA CO Training</b>	<b>Year of most recent audit by CO</b>
<b>Regional Certification Officer (Regional CO)</b>	Jesse Kiernan Organic Chemist, R8 Laboratory 16194 W. 45th Drive, Golden CO Kiernan.jesse@epa.gov 303-312-7767	Organic Chemistry	2007	--	2016
<b>Regional Certification Officer (Regional CO)</b>	Jeff McPherson Aquatic Biologist, R8 Laboratory 16194 W. 45th Drive, Golden CO Mcperson.jeffery@epa.gov 303-312-7752	Microbiology	2009	--	2015
<b>Regional Certification Officer (Regional CO)</b>	Mark Murphy Organic Chemist, R8 Laboratory 16194 W. 45th Drive, Golden CO Murphy.mark@epa.gov 303-312-7775	Organic Chemistry	2007	--	2015
<b>Regional Certification Officer (Regional CO)</b>	David Nguyen Organic Chemist, R8 Laboratory 16194 W. 45th Drive, Golden CO Nguyen.davidd@epa.gov 303-312-7771	Organic Chemistry	2007	--	2015
<b>Regional Certification Officer (Regional CO)</b>	Tom Slabe Microbiologist, R8 Laboratory 16194 W. 45th Drive, Golden CO Slabe.thomas@epa.gov 303-312-7797	Microbiology	2010	--	2015

Title	Name Office/Branch	Area(s) of Responsibility (Specify Chemistry, Microbiology, Radiochemistry, <i>Cryptosporidium</i> , etc.)	Year Passed EPA CO Training	Year Last Audited EPA CO Training	Year of most recent audit by CO
<b>Regional Certification Officer (Regional CO)</b>	Kenneth Dahlin Organic Chemist, R8 Laboratory 16194 W. 45th Drive, Golden CO Dahlin.kenneth@epa.gov 303-312-7774	Organic Chemistry	2011	--	2015

## Attachment D

### Primacy State Drinking Water Laboratory Certification/Accreditation Programs Date of Last Assessment & Number of Laboratories In- and Out-of-State

Primacy State	State Laboratory Certification Program Assessments				Number of Laboratories Certified In State (Out of State)				
	Agency	Assessor	Date of last SLCPA	Date of last signed certificate/report	Chemistry	Microbiology	Radiochemistry	<i>Cryptosporidium</i>	Asbestos
Colorado	CO Department of Public Health and Environment	EPA Region 8	5/14/2014 (previous 2013)	8/14/2014	33(25)	58(4)	3(4)	2(2)	0(2)
Montana	MT Department of Public Health and Human Services	EPA Region 8	2011 Overdue	2006	10(19)	14(3)	0(6)	0(1)	0(3)
North Dakota	ND Department of Health	EPA Region 8	4/4/2016 (previous 2013)	5/5/2016	5(31)	8(1)	0(17)	0(0)	0(1)
South Dakota	SD Department of Health	EPA Region 8	2/13/2013 Overdue	3/25/2013	4(6)	4(3)	1(5)	0(0)	0(3)
Utah	UT Department of Health	NELAP and Region 8	4/2014 (previous 2012)	NELAP – 8/13/2014 EPA - 8/20/2014	22(6)	25(1)	0(5)	0	0
Wyoming	EPA Region 8	OGWDW	No primacy, Region 8 has direct implementation responsibilities	NA	Per 2014 AQ 4 (38)	Per 2014 AQ 14 (26)	Per 2014 AQ 2 (9)	Per 2014 AQ 0 (1)	Not in 2014 AQ

## Attachment E

### Area of Responsibility and Training Status of Certification Officers in Primacy States

Name/Affiliation	State	Area(s) of Responsibility (Specify Chemistry, Microbiology, Radiochemistry, <i>Cryptosporidium</i> , etc.)	Year Passed EPA CO Training	Year Last Audited EPA CO Training
Ben Chouaf	CO	Chemistry Microbiology Radiochemistry <i>Cryptosporidium</i>	2011 2009 ----- 2015	N/A Past due  N/A
Russell Leu	MT	Chemistry - Organics/inorganics	2010	Past due
Curtis Fjelstad	MT	Microbiology	2013	N/A
Cynthia L. Auen	ND	Chemistry	2013	N/A
Lisa Well	ND	Microbiology	2013	N/A
Stacy Ellwanger	SD	Chemistry Radiochemistry	1990s	Past due
Teresa Chicoine	SD	Microbiology	1987	Past due
Kristin Brown - UDOH	UT	Chemistry(Inorganic/Organic) Microbiology Radiochemistry	2001 2002 2006	2013 2014
Robert Aullman	UT	Chemistry(Inorganic/Organic) Microbiology <i>Cryptosporidium</i>	2011 2011 2015	N/A N/A N/A
Alia Rauf	UT	Chemistry (Organic)	2011	N/A